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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,194	08/15/2002	Michel Renard	218874USOPCT	8696
22850 7590 02/12/2007 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER BAUM, STUART F	
			ART UNIT 1638	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/030,194	Applicant(s) RENARD ET AL.	
	Examiner Stuart F. Baum	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-8 and 11-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-8 and 11-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/08/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RCE Acknowledgment

1. The request filed on 11/8/2006 for a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114, based on parent Application No. 10/030,194 is acceptable and a RCE has been established. An action on the RCE follows.

2. Claims 1, 4-8 and 11-16 are pending.

Claims 2-3, and 9-10 have been canceled.

3. Claims 1, 4-8 and 11-16 including SEQ ID NO:5 and SEQ ID NO:4 are examined in the present office action.

Claim Objection

4. Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. All crucifer plants are in the family Brassicaceae but not all species of plants in the family Brassicaceae are crucifers.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 1, 4-8 and 11-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a plant in the family Brassicaceae, wherein the plant comprises a mutant gene encoding a protein comprising the amino acid sequence of SEQ ID NO:7, wherein the gene was mutagenized by chemical mutagenesis, does not reasonably provide enablement for an isolated nucleic acid encoding a protein comprising the amino acid sequence Gly Tyr X₁ Val Glu X₂ in which X₁ represents arginine or asparagines and which X₂ represents a basic amino acid, wherein the sequence is SEQ ID NO:7 or 4, and plant transformation therewith wherein the transformed plant exhibits a reduction in plant size as compared to a wild-type plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to an isolated nucleic acid sequence obtained by mutation of a sequence encoding a plant protein of the GRAS family, wherein the isolated nucleic acid encodes a protein comprising the amino acid sequence Gly Tyr X₁ Val Glu X₂ in which X₁

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represents arginine or asparagines and X₂ represents a basic amino acid, and wherein a plant transformed with said isolated nucleic acid sequence exhibits a reduction in plant size as compared to the wild-type plant, or wherein the nucleic acid sequence encodes the polypeptide represented by SEQ ID NO:4; a plant with reduced development comprising one or more copies of said nucleic acid sequence, or wherein the plant is a mutant plant, or a descendant of the mutant plant comprising one or more copies of said nucleic acid sequence.

The Office interprets claim 14 to be drawn to a mutant plant that is also transformed with said nucleic acid sequence.

Applicants isolated their invention from dwarf plants of the "STELLAR" rapeseed line. The DNA sequence comprises 1716 bp coding sequence listed in SEQ ID NO:1 encoding the BZH polypeptide comprising 572 amino acids of SEQ ID NO:2 (page 7, lines 28-38). Applicants disclose the mutant gene contains a G to A substitution at position 1695 which creates a Glu to Lys amino acid change at position 546, whose sequences are set forth in SEQ ID NO:3 and 4, respectively (page 8, lines 11-23).

The state-of-the-art teaches that transforming a plant with a transcription factor produces unexpected results. Yang et al (2001, PNAS 98(20):11438-11443) teach transgenic rice plants constitutively expressing the REB transcription factor produced mutant plants that were sterile. Yang et al state "Presumably, this aberrant phenotype is because of the constitutive expression of the transcriptional activator REB in all plant cells, causing disturbances of the normal gene expression program during rice development" (page 11443, left column, bottom paragraph). Riechmann et al (2000, Current Opinion in Plant Biology 3:423-434) state "Most importantly, it can be unclear whether a phenotype reflects the true function of a gene or whether it is simply

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caused by interference with unrelated processes. Such problems could be particularly prevalent for transcription factors” (page 427, right column, 3rd full paragraph).

The state-of-the-art teach transforming plants with heterologous genes that are involved in plant development produce unpredictable results. Kano-Murakami et al (1993, FEBS 334:365-368) teach introducing the *Oryza sativa* homeobox 1 (OSH1) gene into tobacco. OSH1 is a rice homologue of the *Knotted-1* homeobox gene from maize and would be encompassed by Applicant’s broad claim language. Kano-Murakami et al teach transgenic tobacco plants comprising the OSH1 gene display a “range of phenotypes which include abnormalities in leaf and petal shape as well as stem height and number” (page 365, right column, 1st paragraph).

In addition, Jaglo et al (2001, Plant Physiology 127:910-917) teach transforming *Brassica* oilseed rape with Arabidopsis CBF genes caused *B. napus* to have enhanced freezing tolerance. But, Jaglo et al state “It is important to bear in mind, however, that constitutive high-level overexpression of the CBF genes can result in undesirable agronomic traits. In Arabidopsis, high-level CVF overexpression can cause a stunted growth phenotype, a decrease in seed yield and a delay in flowering” (sentence bridging the left and right columns on page 915). Jaglo et al continue by disclosing the CBF expressing Brassica plants looked normal while grown in a growth chamber but displayed a stunted growth and delayed flowering phenotypes when grown in a greenhouse (page 915, right column, 1st paragraph).

Applicants have not disclosed when during plant development the claimed nucleic acid needs to be expressed to achieve the desired phenotype. Applicants disclose that the claimed nucleic acid is involved in GA perception and response (page 3 of specification, lines 25-26 and page of specification, lines 4-6) and GA perception and response are also important for other

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plant developmental processes, such as flowering. Therefore, one of skill in the art would have to test a multitude of promoters with different spatial and temporal expression patterns to find one that can be used with Applicants' claimed invention that would yield the expected result.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to first generate a population of seeds in which the genome of said seeds has been mutagenized, and to grow all the plants and select those plants that exhibit a dwarf phenotype or exhibit a reduced development phenotype, to isolate DNA from the multitude of plants that exhibit a reduced development or dwarfed phenotype, and to identify from the isolated DNA those sequences which encode a protein in the GRAS family, and wherein the DNA encodes a protein comprising SEQ ID NO:4 or 7, and then to transform plants with the isolated DNA and to screen the multitude of transformed plants for those that exhibit a dwarf phenotype or a reduced development phenotype, wherein the phenotype is due to the expression of the isolated DNA.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Applicant's arguments filed 11/8/2006 have been fully considered but they are not persuasive. Applicants contend that the procedures for expressing a gene in a plant were well known at the time of filing and as such, the skilled artisan could reliably use the procedures available in the art for expressing the mutant gene of the present invention without undue experimentation (page 14 of Remarks, top paragraph).

The Office contends that there is a large degree of unpredictability associated with Applicants' invention given the fact that Applicants have not transformed a single plant with any of the nucleic acid sequences that are being claimed. As discussed above, the Office contends that the state-of-the-art teaches that there is unpredictability or unexpected results associated with transforming plants with nucleic acids that encode transcription factor, or genes that are involved in plant development or that high level expression of an introduced gene can also produce unexpected results. Applicants have not addressed the issue of when and where the claimed gene has to be expressed for achieving the desired result. One skilled in the art would have to test a multitude of promoters to find one that expresses during the correct developmental time period and correct spatial developmental location so as to produce a plant with a dwarf phenotype. Applicants have indicated that their invention is involved in GA perception and response (page 3 of specification, lines 25-26 and page 6 of specification, lines 4-6) but one skilled in the art recognizes that GA perception and response are also important for other developmental processes, e.g., flowering. Therefore, without additional guidance for when and where the claimed invention should be expressed, one of ordinary skill in the art would require undue trial and error experimentation to practice the claimed invention.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 5-8, 11 and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Foisset et al (1995, Theor. Appl. Genet. 91(5):756-761, listed in the IDS) taken with the evidence of Barret et al (1998, Theor. Appl. Genet. 97:828-833).

The claims are drawn to a plant with reduced development comprising one or more copies of a nucleic acid sequence obtained by mutation of a sequence encoding a plant protein of the GRAS family, wherein the wild type protein comprises the peptide sequence Gly Tyr X₁ Val Glu Glu of SEQ ID NO:5 in which X₁ represents arginine or asparagines wherein said mutation results in a modification of said sequence such that the nucleic acid sequence encodes a mutant protein comprising SEQ ID NO:7 comprising the peptide sequence Gly Tyr X₁ Val Glu X₂ in which X₂ represents a basic amino acid, or wherein the plant is a crucifer, or wherein the plant is rapeseed, or wherein X₂ represents lysine, or wherein said plant is obtained by chemical mutagenesis, or a descendant of said plant comprising one or more copies of said nucleic acid sequence,

Foisset et al disclose a dwarf Brassica napus plant comprising a mutant *breizh* (*bzh*) gene obtained by chemical mutagenesis (page 756, right column, 1st full paragraph). Because of Applicants' admitted statement "The inventors have now characterized and sequenced the *BZH* gene of *B. napus*, and its mutant allele *bzh*, associated with the dwarf phenotype previously observed by Foisset et al (1995, ...) (page 3, lines 30-33), the Office contends Foisset et al disclose a plant with said mutant gene. In particular, Foisset et al disclose a rapeseed plant, that is a crucifer, or descendants of said plant comprising the mutant *bzh* gene (page 757, left column,

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2nd full paragraph). Barret et al teach that the *Bzh* gene is semi-dominant by stating "...and heterozygous (semidwarf, *Bzh/bzh*) plants..." (page 828, right column, top paragraph). The Office contends the instant application appears to merely be a further characterization of plants containing the same genetic locus as the prior art plants. See *In re Cruciferous Sprout Litigation*, 64 USPQ2d 1202, (Fed. Cir. 2002), which teaches that newly recognized constituents or properties of a prior art product are inherent properties which do not render claims to that product patentable, and as such, Foisset et al anticipate the claimed invention.

Applicant's arguments filed 11/8/2006 have been fully considered but they are not persuasive.

Applicants contend Foisset et al is clearly insufficient to enable one of ordinary skill in the art to reproduce the dwarf rapeseed plants and does not put the public in possession of the subject matter of claims 14-16 (page 15 of Remarks, 1st full paragraph). Applicants contend Foisset et al fail to provide evidence that the resultant dwarf phenotype is the result of a mutant *bzh* gene. Applicants contend it is only the present invention that has isolated, characterized and determined the link between dwarfism and the specifically claimed mutant *bzh* gene (paragraph bridging pages 15 and 16 of Remarks). Applicants contend that Foisset et al is not a sufficient disclosure to enable the skilled artisan to produce a dwarf phenotype which is the result of a mutant *bzh* gene as disclosed in the present application (page 16, 1st, 2nd and 3rd paragraphs). Applicants contend Foisset et al do not disclose or suggest that the *bzh* mutation has a characteristic of "semi-dominance" and insensitivity to gibberellins (page 16 of Remarks, last sentence).

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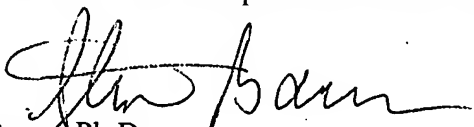
The Office contends that Foisset et al discloses the mutant plant that Applicants are claiming because Applicants clearly state in the specification that their invention is the *Bzh* gene that is responsible for the mutant phenotype (see above). Foisset et al disclose that the mutation is the result of treatment with the chemical mutagen MSE (page 757, left column, 1st paragraph of Materials and Methods). As stated above, "newly recognized constituents or properties of a prior art product are inherent properties which do not render claims to that product patentable". Lastly, Barret et al teach that the *bzh* mutation is semi-dominant and therefore, Applicants' product is anticipated by Foisset et al.

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.


Stuart F. Baum Ph.D.
Primary Examiner
Art Unit 1638
January 28, 2007

STUART F BAUM, PH.D
PRIMARY EXAMINER